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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,176	02/10/2000	Steven Pirie-Shepherd	05940-0141	4843

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/502,176

Applicant(s)

PIRIE-SHEPHERD ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6-12,15,16 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 is/are allowed.
- 6) ☒ Claim(s) 1-4,6-12,15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Response to Arguments***

1. Claims 1-4, 6-13, 15, 16 and 27 are pending.  
Claims 1-4, 6-12, 15, 16 and 27 have been amended.  
Claims 5, 13, 14, 17-26 and 28 have been cancelled.  
Claims 1-4, 6-12, 15, 16 and 27 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The Examiner acknowledges Applicants' amendment to the specification correctly identifying kringles 1-3. The kringles listed in the figures do not include the entire human plasminogen, kringles 1-5. This correction to the specification and claims is not regarded as new matter.

Given the correct identification of the kringles a new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Priority***

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged and granted. Provisional applications, 60/119,562 (filed February 10, 1999) and 60/128,062 (filed April 7, 1999) upon which priority is claimed

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provide adequate support for the examined claims. Priority of the examined claims are awarded February 10, 1999.

### ***Drawings***

5. The corrected or substitute drawings for Figures 2, 3 and 4 were received on February 11, 2002. These drawings have been reviewed by the draftsman and deemed approved.

### ***Specification***

6. The disclosure continues to be objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 17, line 32 and page 35, lines 15 and 34. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

7. The disclosure is no longer objected to because Applicants have amended the specification to reflect consistency between the figures the brief description of the figures.

### ***Withdrawn Rejections***

#### ***Claim Rejections - 35 USC § 112***

8. The rejection of claims 1-4, 6-12, 15, 16 and 27 under 35 U.S.C. 112, second paragraph, set forth in Paper number 11 (mailed September 7, 2001) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 has been cancelled.

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***Claim Rejections - 35 USC § 102***

9. The rejection of claims 15 and 16 under 35 U.S.C. 102(b) as being anticipated by Sim et al. (Cancer Research 57:1329-1334, April 1, 1997) is withdrawn in light of Applicants' arguments.

10. The rejection of claims 1-4, 6, 8, 9, 12, 15 and 16 under 35 U.S.C. 102(b) as being anticipated by Accession number P00747 is withdrawn in light of Applicants' arguments. Claim 5 has been cancelled.

***New Grounds of Rejection and Maintained Rejections***

***Claim Rejections - 35 USC § 112***

11. Claims 1-4, 6-12, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 is vague and indefinite in the recitation "smaller amount".

What quantity is considered a smaller amount? Accordingly, the metes and bounds of the claim cannot be determined.

b. Claims 6 and 7 are indefinite because they both reference claim 5, a cancelled claim.

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**Claim Rejections - 35 USC § 102**

12. The rejection of claims 1-4, 6, 8, 9 and 12 under 35 U.S.C. 102(b) as being anticipated Sim et al. (Cancer Research 57:1329-1334, April 1, 1997) is maintained.

Applicants argue that the fragment of Sim is a recombinant protein comprising kringles 1-4 of human plasminogen. Moreover, Applicants argue that Sim does not teach or suggest the use of deglycosylated or unglycosylated form of angiostatin protein for suppression of angiogenesis *in vitro* or *in vivo*. Applicants rely on passages within the Sim reference to support their assertions and denote pages and columns where this information is found. These arguments are found to be partially persuasive.

Sim does note on page 1331, column 1, last full sentence "...recombinant Angiostatin protein consisting of the doublet was used in all *in vitro* and *in vivo* assays...", as pointed out by Applicants. The Examiner does concur with that fact. However, as set forth in the first action on the merits mailed September 7, 2001 as Paper number 11 Sim discloses a composition comprising recombinant angiostatin (see page 1330, column 1, entire section of "Purification of Recombinant..."). The caption of Figure 2 on page 1331 provides information reflective of Sim purifying deglycosylated, as well as glycosylated recombinant Angiostatin (also see bridging paragraph of page 1331 and 1332, especially explanation of Figure 2). In view of the open language "composition comprising..." the claim reads on kringles 1-3, as well as additional kringles.

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Furthermore, Sim digested the recombinant Angiostatin protein with endoglycosidase H and O-glycanase with prior neuraminidase treatment to remove carbohydrate moieties (see page 1331, column 2, bridging sentence and first two full sentences). Consistent with this enzyme treatment the deglycosylated fragment inherently lacked a bisialylated-biantennary glycan and a N-linked carbohydrate moiety with an amino acid substitution at an amino acid position corresponding to the N-glycosylation site of human plasminogen. Sim states in the abstract that the disclosed recombinant protein comprises kringles 1-4 of human plasminogen starting at amino acid residue 93, this is within the range of at approximately amino acid 87 of human plasminogen.

13. Claims 6, 7, 10, 11, 15 and 16 are free of the art.

***Allowable Subject Matter***

14. Claim 27 is allowed.

***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory


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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Alana M. Harris, Ph.D.  
May 20, 2002